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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,933	02/10/2004	Michael D. Kluetz	CGL03/0339US01	3155

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EXAMINER	
CHUI, MEI PING	

ART UNIT	PAPER NUMBER
1609	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/775,933	KLUETZ ET AL.	
	Examiner	Art Unit	
	Helen Mei-Ping Chui	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 January 1983*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-83* is/are pending in the application.

4a) Of the above claim(s) *21-69 and 72-83* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20,70 and 71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/26/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Action

Applicant's election of species of claim 15 and invention I with traverse, which encompasses claims 1-16 and 70-71, in the reply filed on 05/03/2007 is acknowledged. The traversal is on the ground(s) that there would not be a serious burden to examine all the claims together of the present application (see Page 1 of the Response). While searching the art for the composition of invention I, the Examiner found art that reads on claims 17-20, therefore these claims are rejoined with invention I.

The requirement for restriction is still deemed proper and is therefore made FINAL.

Status of Claims

Accordingly, claims 1-20 and 70-71 are presented for examination on the merits for patentability as they read upon the elected subject matter and claims 21-69 and 72-83 directed to non-elected inventions are withdrawn.

Objection to Specification

The use of the following trademarks has been noted in this application: MICROTEC page 10, line 30), NETZSCH, BAUERMEISTER, HOSOKAWA-BEPEX

(Page 11, line 1 and 18) and PARR (Page 13, line 28). They should be denoted with the ® symbol, or alternately, written in all capital letters wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Also, objection of the following informality: the spelling of "T tal" in the specification (Page 16, Table I) should be changed to "Total". Likewise, the spelling of "MicrotecMicrotec" (page 10, line 30) is unclear whether there should be a hyphen between "Microtec" or there should be only one "Microtec" in the spelling. Applicant is requested to correct the typographical error.

Claim Rejections - 35 USC § 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All dependent claims are included in this rejection.

The term " acceptable mouthfeel" in claim 1 is a relative term which renders the claim indefinite. The term "acceptable mouthfeel" is not defined by the claim, the

specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "total specific surface area" in claims 10-12 is not defined in the claim, and the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "no or only a slight detectable chalky mouthfeel" in claim 71 is a relative term which renders the claim indefinite. The term " no or only a slight detectable chalky mouthfeel " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-20 and 70-71 are rejected under 35 U.S.C. 103(a) as being unpatentable Tiainen et al. (U.S. Patent No. 6,129,944 on 10/10/2000) in view of Lerchenfeld et al. (U.S. Patent Application No. 2003/0232118 published on 12/18/2003), further in view of Anderson et al. (The Journal of Nutrition, 1999, 129:1457S-1466S) and Haarasilta et al. (WO 98/58554 published on 12/30/1998).

Applicant Claims

Applicants claim a composition comprising particulate plant sterol(s) having a particle size distribution less than 35 μm in diameter, wherein said composition is in dispersible aqueous, powder, food or beverage medium.

Determination of the scope and content of the prior art (MPEP 2141.01)

Tiainen et al. teach a product containing a microcrystalline plant sterol, which has the volumetric mean particle size less than 35 μm in diameter (column 2, line 59-64). Tiainen et al. further teach that the preparation of a microcrystalline plant sterol composition results in two different particles size distribution peaks, in which one having diameter between about 2 μm to about 3 μm and the other one having diameter

between about 4 to about 10 μm (Figure 2, Example 3).

Tiainen et al. teach that the microcrystalline plant sterols do not generate a powdery or sandy taste; thus do not affect the mouth-feel of the final edible products (column 10, Example 13).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

Tiainen et al. does not expressly teach the volume or mass to weighted particle size distribution of said plant sterol(s), nor the surface area to weighted particle size diameter of said plant sterols. However, the size of microcrystalline plant sterol particles disclosed in reference of Tiainen falls within the particles' size range in the instant claims.

Lerchenfeld et al. teach a homogenized composition comprising a hydrophobic plant sterol, such as beverage juice (page 2: paragraphs 22, line 7 and page 9, claims 46-49). The plant sterol particulates showed a multi-peak volume-weighted differentiation distribution with the composition (see figure 2, sheet 2 of 2). Lerchenfeld et al. also teach that the plant sterol is an aqueous dispersion, where the particle size is from about 0.1 to about 50 μm in diameter; and more than 50 % of said plant sterol particles within this range possess a diameter from about 0.2 to about 10 μm (Page 2, paragraph 20, line 23-26; page 3, paragraph 26, line 6-8 and page 8-9, claims 37-39).

Anderson et al. teach that non-fiber plant sterols have been shown, clinically, to decrease cholesterol absorption, thus have a protective role in reducing the risk of cardiovascular diseases (page 1461S, Non-Fiber Plant section: paragraphs 2-3).

Haarasilta et al. teach a premix composition useful in food industry containing plant sterol and foodstuff ingredients, such as cereal, leguminous plant, milk powder, egg white and other edible or bakery products, etc (page 1:Field of Invention).

Finding of prima facie obviousness Rationale and Motivation (MPEP 2142-2143)

There is no unobvious or unexpected result seen from such a particle size distribution in the claimed invention; therefore, from the teachings of the cited references combined together, it is obvious that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Furthermore, optimizing the particle sizes distribution in respect to the volume and surface area of said plant sterols composition is a routine practice that would be obvious for a person of ordinary skill in the art to employ.

One ordinary skill in the art would expect that a finely ground plant sterol particle would have a distribution of particle sizes. It is also obvious to one of ordinary skill in the art to incorporate such finely ground plant sterol particles, which is well known to have an effect in reducing dietary health risk, in edible foods or beverages without affecting the mouth-feel of the products.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made that every element of the invention, as a whole, has been fairly suggested by the combined teachings of the cited references.

Conclusion

No claims are allowed.

Contact Information

Any inquiry concerning this communication from the Examiner should direct to Helen Mei-Ping Chui whose telephone number is 571-272-9078. The examiner can normally be reached on Monday-Thursday (7:30 am – 5:00 pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where the application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either PRIVATE PAIR or PUBLIC PAIR. Status information for unpublished applications is available through PRIVATE PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the PRIVATE PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H.C.

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER